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Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

VIA FEDERAL EXPRESS

Ref: Customs Entry No. EM8-0002116-1
Product: Contact Lenses

WARNING LETTER

FLA-01-33

February 12, 2001

Carlos Pietrocemoli, President
Optilux (c/o Advance Import & Export)
8438 N.W. 68th Street
Miami, Florida 33166

Dear Mr. Pietrocemoli:

The Food and Drug Administration (FDA) attempted to examine a shipment of contact lenses offered for entry into the United States by your firm on August 10, 2000, under the above referenced entry number, and found that the entire shipment was not available for FDA examination. Title 21, Code of Federal Regulations (21 CFR), Section 1.90 requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We have requested the U. S. Customs Service (Customs) to order redelivery of this shipment (copy enclosed).

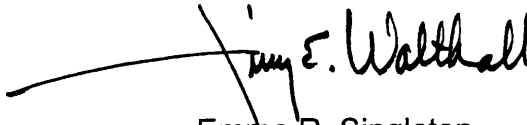
Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction or automatic detention of further shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter outlining the specific steps you have taken to correct the violation. Your response should include an explanation of each step being taken to prevent the recurrence of the violation. In the event that the product is still available for examination, you should inform Customs and FDA if and when redelivery is accomplished.

Carlos Pietrocemoli
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Your written reply should be addressed to the Food and Drug Administration,
Attn: Carlos W. Hernandez, Compliance Officer, P. O. Box 59-2256, Miami,
Florida 33159-2256.

Sincerely,


Fax Emma R. Singleton
Director, Florida District

cc: Thomas Winkowski
Port Director
U. S. Customs Service
P. O. Box 02-580
Miami, Florida 33102-5280

Paolo Dal Fara (CHB)
1465 N.W. 97th Avenue
Miami, Florida 33172